

USE ONLY  
OGC Has Reviewed  
CRC, 10/14/2003

10 OCT 1975

STATINTL

MEMORANDUM FOR: [REDACTED]

Office of Legislative Counsel

SUBJECT : Proposed Senate Bill by Senator Kennedy  
on the Protection of Human Subjects

REFERENCE : OLC 75-2460

1. The following comments which represent the views of the Office of Medical Services are forwarded for your consideration in the hope that they will provide constructive suggestions. At the outset I wish to emphasize that I applaud the general intent of Senator Kennedy's proposed Bill. Specifically, Sections 482 and 483 are matters of deep concern not only to health professionals but to the public in general. The legal, ethical and professional aspects of human experimentation are currently ranked among the most pressing problems in our society and is being addressed by a number of the most prestigious organizations and individuals concerned with these problems. The Office of Medical Services would certainly welcome and comply with established guidelines to the extent that they can be defined in a meaningful way.

2. Whether a Presidential Commission can add further focus and attention on the problem is hard to judge. If the sole purpose of the Bill is to assure compliance by the Central Intelligence Agency then it would appear to me that there is probably a simpler way to achieve that goal through existing Executive or Congressional direction.

3. If it is deemed advisable to establish a Presidential Commission then I would like to raise certain questions about the Bill as follows:

a. It strikes me that it might be inappropriate to include the Director of Central Intelligence as a

ADMINISTRATIVE-INTERNAL USE ONLY

SUBJECT: Proposed Senate Bill by Senator Kennedy on the Protection of Human Subjects

member of the Commission as it would probably lead to charges that the Agency is involving itself in domestic matters. This must be weighed against the advantages of having the Agency's views represented directly on the Commission.

b. I have doubts as to whether a Commission of this size meeting periodically would be able to address in any detail all of the various aspects of human experimentation in depth unless it had a very substantial full-time staff. It has been our experience that policing the compliance of contractors, be they government or private, can be done quite effectively by our own staff given the appropriate guidelines.

c. Section 481 (2)(g) deals with the question of providing National Security Information to the full Commission and in some cases disclosure. This area should be examined most carefully since our experience resulting from the Katzenbach Report showed that some institutions were unwilling to undertake well-controlled and unclassified research if their institution would be openly identified with the Central Intelligence Agency. It is likely that outstanding research institutions would be even more reluctant to provide consultation and support in today's climate with the net effect that CIA will find it increasingly difficult to engage the services of organizations committed to the standards intended by Senator Kennedy.

4. I note that the proposed Bill recommends that the Commission investigate the use of psychosurgery but excludes electric shock treatment and other forms of brain surgery. I suspect that I share the same concerns about psychosurgery but question whether the Bill should proscribe a specific area of investigation and exclude other forms of therapy which are currently under review by health professionals.

5. I am unable to comment on whether a Presidential

SUBJECT: Proposed Senate Bill by Senator Kennedy on the Protection of Human Subjects

Commission would provide benefits and direction beyond those already incorporated under the National Research Act but assume that this will be spelled out in some detail.

STATINTL

[redacted] M.D.

[redacted] M.D.  
Deputy Director of Medical Services

STATINTL

OMS/SI [redacted] :ned

Distribution:

Orig & 1 - Addressee  
✓ - D/MS Files

94th CONGRESS  
1st SESSION

S.

(Note.—Fill in all blank lines except those provided for the date, number, and reference of bill.)

IN THE SENATE OF THE UNITED STATES

Mr. \_\_\_\_\_

introduced the following bill; which was read twice and referred to the Committee on \_\_\_\_\_

**A BILL**

To amend the Public Health Service Act to establish the President's Commission for the protection of human subjects involved in biomedical and behavioral research, and for other purposes.

(Insert title of bill here)

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "President's Commission for the Protection of Human Subjects of Biomedical and Behavioral Research Act of 1975".*

AMENDMENT TO THE PUBLIC HEALTH SERVICE ACT

Sec. 2. Title IV of the Public Health Service Act is amended by inserting the following new part at the end thereof:

"PART J--PROTECTION OF HUMAN SUBJECTS

"Establishment of Commission

"Sec. 481. (a) There is established a Commission to be known as the President's Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (hereinafter in this title referred to as the "Commission"). The Commission shall be composed of--

7/12/2  
AS/AB/AB

"(1) four members of the Senate appointed by the President of the Senate; and

"(2) four members of the House of Representatives appointed by the Speaker of the House of Representatives; and

"(3) the Secretary of the Department of Health, Education and Welfare, the Secretary of Defense, the Director of the Central Intelligence Agency, and the Administrator of the Veteran's Administration; and

"(4) eleven members appointed by the President of the United States with the advice and consent of the Senate.

"The President shall select members of the Commission under paragraph (4) from individuals distinguished in the fields of medicine, law, ethics, theology, the biological, physical, behavioral and social sciences, philosophy, humanities, health administration, government, and public affairs; but five (and not more than five) of the members of the Commission shall be individuals who are or who have been engaged in biomedical or behavioral research involving human subjects. Until such time as the President acts to appoint members of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research are deemed members of the Commission as of the date of enactment of this Act.

"(b) The term of office of each member of the Board shall be four years; except that (1) any member appointed to fill a vacancy occurring prior to the expiration of the term for which his predecessor was appointed shall be appointed for the remainder of such term; (2) the terms of office of members first taking office shall begin on the date of appointment and shall expire, as designated at the time of their appointment, four at the end of one year, four at the end of two years, and three at the end of four years; and (3) a member whose term has expired may serve until his successor has qualified.

"(c)(1) The President shall designate one of the members of the Commission as Chairman, and one as Vice Chairman. Seven members of the Commission shall constitute a quorum, but a lesser number may conduct hearings.

"(d) Members of the Commission who are Members of Congress or full-time officers or employees of the United States shall serve without additional compensation but shall be reimbursed for travel, subsistence, and other necessary expenses incurred in the performance of the duties vested in the Commission. Members of the Commission from private life shall receive \$100 per diem while engaged in the actual performance of the duties vested in the Commission, plus reimbursement for travel subsistence and other necessary expenses incurred in the performance of such duties.

"(e) The Commission shall meet at the call of the Chairman or at the call of a majority of the members thereof.

"(f)(1) The Commission shall have the power to appoint and fix the compensation of such personnel as it deems advisable, without regard to the provisions of title 5, United States Code, governing appointments in the competitive service, and the provisions of chapter 51 and subchapter III of chapter 53 of such title, relating to classification and General Schedule pay rates.

"(2) The Commission may procure, in accordance with the provisions of section 3109 of title 5, United States Code, the temporary or intermittent services of experts or consultants. Persons so employed shall receive compensation at a rate to be fixed by the Commission, but not in excess of \$100 per diem, including travelttime. While away from his home or regular place of business in the performance of services for the Commission, any such person may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703(b) of title 5, United States Code, for persons in the Government service employed intermittently.

"(g) The Commission may secure directly from any department or agency of the United States information necessary to enable it to carry out its duties. Upon request of the Chairman of the Commission, each and every agency or department of the United States shall furnish all information requested by the Commission which is necessary to enable it to carry out its duties. If any information so requested has been deemed to be classified for any purpose (including national security) by such agency or department, such information shall be furnished to the Special Classified Information Committee of the Commission (hereinafter in this section referred to as the "Special Committee"), which shall be composed of those members of the Commission who are appointed under paragraphs (1), (2), and (3) of section 481 (a). Eight members of the Special Committee shall constitute a quorum, but a lesser number may conduct hearings. By a majority decision of the Special Committee, such information shall be disclosed without regard to the sensitivity of such information to the full Commission upon a finding by the Special Committee that there is or will be an adverse impact upon the protection of human subjects of research.

"Commission Duties

"Sec. 482. (a) The Commission shall carry out the following:

"(1)(A) The Commission shall (i) conduct a comprehensive investigation and study to identify the basic ethical principles which should underlie the conduct of biomedical and behavioral research involving human subjects, (ii) develop guidelines which should be followed in such research to assure that it is conducted in accordance with such principles, and (iii) make recommendations to the appropriate agency or department for such administrative action as may be appropriate to apply such guidelines to biomedical and behavioral research conducted or supported under programs administered by the appropriate agency or department, and (II) concerning any other matter pertaining to the protection of human subjects of biomedical and behavioral research.

"(B) In carrying out subparagraph (A), the Commission shall consider at least the following:

"(i) The boundaries between biomedical or behavioral research involving human subjects and the accepted and routine practice of medicine.

"(ii) The role of assessment of risk-benefit criteria in the determination of the appropriateness of research involving human subjects.

"(iii) Appropriate guidelines for the selection of human subjects for participation in biomedical and behavioral research.

"(iv) The nature and definition of informed consent in various research settings.

"(v) Mechanisms for evaluating and monitoring the performance of Institutional Review Boards established in accordance with section 474 of this Act and appropriate enforcement mechanisms for carrying out their decisions.

"(C) The Commission shall consider the appropriateness of applying the principles and guidelines identified and developed under subparagraph (A) to the delivery of health services to patients under programs conducted or supported by the Secretary of HEW and shall review and suggest the ethical, social and legal implications of all biomedical and behavioral research on human subjects conducted by and through any Federal agency (including contractors) for which any Federal funds are to be appropriated.

"(2) The Commission shall identify the requirements for informed consent to participation in biomedical and behavioral research by children, prisoners, military personnel, and the institutionalized mentally infirm. The Commission shall investigate and study biomedical and behavioral research conducted or supported under programs administered by the Secretary and involving children, prisoners, military personnel, and the institutionalized mentally infirm to determine the nature of the

consent obtained from such persons or their legal representatives before such persons were involved in such research; the adequacy of the information given them respecting the nature and purpose of the research, procedures to be used, risks and discomforts, anticipated benefits from the research, and other matters necessary for informed consent; and the competence and the freedom of the persons to make a choice for or against involvement in such research. On the basis of such investigation and study, the Commission shall make such recommendations to any department or agency of the United States as it determines appropriate to assure that biomedical and behavioral research conducted by or supported under the appropriate department or agency of the United States meets the requirements respecting informed consent identified by the Commission. For purposes of this paragraph, the term 'children' means individuals who have not attained the legal age of consent to participate in research as determined under the applicable law of the jurisdiction in which the research is to be conducted; the term 'prisoner' means individuals involuntarily confined in correctional institutions or facilities (as defined in section 601 of the Omnibus Crime Control and Safe Streets Act of 1968 (43 U.S.C. 3781)); and the term 'institutionalized mentally infirm' includes individuals who are mentally ill, mentally retarded, emotionally disturbed, psychotic, or senile, or who have other impairments of a similar nature and who reside as patients in an institution; the term 'military personnel' means individuals who are active and inactive members of the U.S. Armed Forces, veterans of the U.S. Armed Forces, and employees and agents of the Central Intelligence Agency.

"(3) The Commission shall conduct an investigation and study of the use of psychosurgery in the United States during the five-year period ending December 31, 1972. The Commission shall determine the appropriateness of its use, evaluate the need for it, and recommend to the Secretary policies defining the circumstances (if any) under which its use may be appropriate. For

purposes of this paragraph, the term "psychosurgery" means brain surgery on (1) normal brain tissue of an individual who does not suffer from any physical disease for the purpose of changing or controlling the behavior or emotions of such individual, or (2) diseased brain tissue of an individual, if the sole object of the performance of such surgery is to control, change, or affect any behavioral or emotional disturbance of such individual. Such term does not include brain surgery designed to cure or ameliorate the effects of epilepsy and electric shock treatments.

"Special Study

"Sec. 483. The Commission shall undertake a comprehensive study of the ethical, social, and legal implications of advances in biomedical and behavioral research and technology. Such study shall include—

"(1) an analysis and evaluation of scientific and technological advances in past, present, and projected biomedical and behavioral research and services;

"(2) an analysis and evaluation of the implications of such advances, both for individuals and for society;

"(3) an analysis and evaluation of laws and moral and ethical principles governing the use of technology in medical practice;

"(4) an analysis and evaluation of public understanding of and attitudes toward such implications and laws and principles; and

"(5) an analysis and evaluation of implications for public policy of such findings as are made by the Commission with respect to advances in biomedical and behavioral research and technology and public attitudes toward such advances.

"Administrative Provisions

"Sec. 484. (a). The Commission may for the purpose of carrying out its duties hold such hearings, sit and act at such times and places, take such testimony, and receive such evidence as the Commission deems advisable.

"(b) Within sixty days of the receipt of any recommendation made by the Commission under section 482, the appropriate department or agency of the United States shall publish it in the Federal Register and provide opportunity for interested persons to submit written data, views, and arguments with respect to such recommendation. The appropriate department or agency of the United States shall (1) determine whether the administrative action proposed by such recommendation is appropriate to assure the protection of human subjects of biomedical and behavioral research conducted or supported under programs administered by it, and (2) if it determines that such action is not so appropriate, publish in the Federal Register such determination together with an adequate statement of the reasons for its determination. If the appropriate department or agency of the United States determines that administrative action recommended by the Commission should be undertaken by it, it shall undertake such action as expeditiously as is feasible.

"Authority to Contract

"Sec. 485. The Commission may contract for the study and design of mechanisms to be included in such recommendations.

"Transfer of Functions

"Sec. 486. The functions, powers, and duties of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (88 Stat. 343-351) shall be transferred to the Commission."

MISCELLANEOUS

Sec. 3. (a) Part A of title III of the National Research Act (42 U.S.C. 289L) is repealed.

(b) Sections 211 and 213 of the National Research Act are repealed.

